bound to a synthetic receptor and being produced and administered in accordance with the method of claim 34.

39. (amended) A multi-prodrug complex for administration to an organism, said multi-prodrug complex comprising at least two prodrug complexes, wherein at least one of the prodrug complexes is produced and administered in accordance with the method of claim 34.

REMARKS

Claims 30-41 are pending in the instant application. Claims 30-33 and 41 have been withdrawn from consideration by the Examiner and subsequently canceled, without prejudice, by Applicant in this amendment. Claims 34-40 have been rejected. Claims 34, 36, 37 and 39 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement dated March 27, 2002 and withdrawn from consideration claims 30-33 and 41. Accordingly, in an earnest effort to advance the prosecution of this case, Applicant has canceled claims 30-33 and 41, without prejudice. Claims 36, 37 and 39 have also been amended to delete dependency to claims 30 and 32. However,

Applicant reserves the right to file a divisional application to the canceled subject matter in light of the finality of this Restriction Requirement.

II. Rejection of Claims 34-40 under 35 U.S.C. § 102(b) and § 103

The Examiner has maintained the rejection of claims 34-40 under 35 U.S.C.§ 102(b) as being clearly anticipated by Morgan, Jr. et al. (U.S. Patent 5,106,951). The Examiner has also maintained the rejection of claims 34-40 under 35 U.S.C. § 103(a) as being unpatentable over Morgan Jr. et al. (U.S. Patent 5,106,951). Arguments presented by Applicant in the response filed November 2, 2001 were found unconvincing by the Examiner, as the Examiner suggests that the antibody-csDBM of Morgan is considered to meet the "antibody fragment" limitation of the instant claims.

Applicant respectfully disagrees.

MPEP § 2111.01 requires that the words of a claim must be given their "plain meaning" unless they are defined in the specification. "In other words, they must be read as they would be interpreted by those of ordinary skill in the art." See MPEP § 2111.01 and In re Sneed, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983). Contrary to the Examiner's suggestion, one of ordinary skill in the art would **not** consider the antibody-csDBM

of Morgan Jr. et al. to meet the "antibody-fragment" limitation of the instant claims.

Antibody-fragment is a term of art defined by industry leaders in references such as U.S. Patent 5,855,577 and U.S. Patent 4,741,900.

U.S. Patent 5,855,577 teaches that antibody fragments contain the idiotype or antigen binding region of the molecule and can be generated by known techniques. As taught therein, such fragments include, but are not limited to, the F(ab')2 fragment which can be produced by pepsin digestion of the antibody molecule; the Fab' fragments which can be generated by reducing the disulfide bridges of the F(ab')2 fragment, and the 2 Fab or Fab fragments which can be generated by treating the antibody molecule with papain and a reducing agent.

As taught in U.S. 4,741,900, the Fab' fragments of IgG immunoglobulins are obtained by cleaving the antibody molecule with pepsin (resulting in a bivalent fragment, $(Fab')_2$) or with papain (resulting in 2 univalent fragments, 2 Fab). The bivalent $(Fab')_2$ fragment can be split by mild reduction of one or a few disulfide bonds to yield univalent Fab' fragments. U.S. Patent 4,741,900 also teaches that Fab and $(Fab')_2$ fragments are smaller than a whole antibody molecule and, therefore, permeate the

target site or tissue more easily.

In contrast, the immunoconjugates of Morgan Jr. et al. comprise either a targeting protein such as an antibody or antibody fragment; a moiety termed a drug binding molecule of complementary structure (abbreviated csDBM), which is covalently bound to the antibody or carrier, and a drug noncovalently complexed to the csDBM (see col. 4, lines 61-67 of the '951 patent); or, alternatively, a drug first bound through covalent bonds to an antibody or carrier and then complexed with a csDBM (see col. 4, line 67, through 5, line 2). Accordingly, the term "antibody fragment", when read as would be interpreted by one of ordinary skill as required by MPEP 2111.01, clearly does not encompass the immunoconjugates of Morgan Jr. et al.

However, in an earnest effort to gain allowance of at least a portion of the subject matter of the pending claims, Applicant has amended claim 34 to remove the phrase "antibody fragment". This amendment is being made solely to further the prosecution of this case and in no way should be construed as an admission by Applicant that antibody fragments are outside the scope of his invention or that an embodiment comprising an antibody fragment is not patentable. In fact, Applicant reserves the right to file a continuation application to prosecute this subject matter

separately.

Withdrawal of the rejections under 35 U.S.C. § 102(b) and 103(a) is respectfully requested in light of this claim amendment.

III. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Respectfully submitted,

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Date: **October 16, 2002**

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 30-33 and 41, without prejudice.

Please amend the claims as follows:

34. (amended) A method of producing and administering a prodrug complex comprising:

(a) identifying a drug;

(b) selecting a synthetic receptor that specifically binds the drug via a saturable, noncovalent interaction between the drug and the synthetic receptor that can be competitively inhibited by structural analogs of the drug, said synthetic receptor being selected from the group consisting of antibodies, ~~antibody fragments,~~ oligonucleotides and oligosaccharides;

(c) specifically binding the identified drug to the selected synthetic receptor to form a prodrug complex; and

(d) administering the prodrug complex to an organism.

36. (amended) A method of producing a multi-prodrug complex for administration to an organism, said multi-prodrug complex comprising at least two prodrug complexes, wherein at least one of the prodrug complexes is produced and administered in accordance with the method of claim ~~30, 32 or~~ 34.

37. (amended) A prodrug complex for administration to an

organism, said prodrug complex comprising a drug specifically bound to a synthetic receptor and being produced and administered in accordance with the method of claim ~~30, 32 or~~ 34.

39. (amended) A multi-prodrug complex for administration to an organism, said multi-prodrug complex comprising at least two prodrug complexes, wherein at least one of the prodrug complexes is produced and administered in accordance with the method of claim ~~30, 32 or~~ 34.